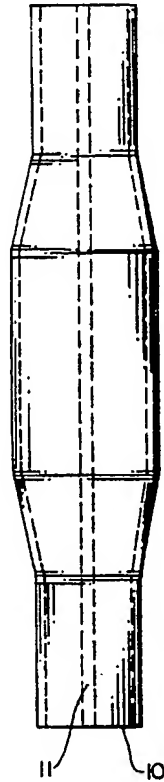


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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 25/00	A1	(11) International Publication Number: WO 92/19306 (43) International Publication Date: 12 November 1992 (12.11.92)
(21) International Application Number: PCT/US92/02970 (22) International Filing Date: 13 April 1992 (13.04.92) (30) Priority data: 692,015 26 April 1991 (26.04.91) US (71)(72) Applicant and Inventor: GAHARA, William, J. [US/US]; 10 Mountain Laurels, Nashua, NH 03062 (US). (74) Agents: SOLOWAY, Norman, P. et al.; Hayes, Soloway, Hennessey & Hage, 175 Canal Street, Manchester, NH 03101-2335 (US).		(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i>
(54) Title: COLLAPSIBLE BALLOON CATHETERS (57) Abstract <p>A flexible plastic inflatable and collapsible medical dilatation balloon (10) and balloon catheter wherein the internal surface of the balloon has been formed with a longitudinal geometry that prevents a flat collapsed configuration of the balloon. The internal surface of the balloon is imparted with a small raised rib (11) configuration, which maintains a minimal contact with the internal surface of the balloon, so that the ribs remain in place along the length of the balloon. The geometry so formed on the internal surface of the balloon also increases the pressures the balloon would normally withstand when the balloon is inflated to dilate a vein or artery. The internal surface geometry can be manufactured by extrusion methods.</p> 		

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1 COLLAPSIBLE BALLOON CATHETERS

2 Background of the Invention

3 Field of the Invention

4 This invention relates to balloons and to balloon
5 catheters which are useful in medical dilatation
6 procedures and is more particularly concerned with the
7 development of a collapsible dilatation balloon that can
8 withstand significant inflation pressures and upon
9 deflation avoids the problem of "winging", that is the
10 development of flat, lateral portions projecting laterally
11 outward beyond the rest of the catheter.

12 Description of the Prior Art

13 Balloon catheters are finding increasing use in
14 medical procedures such as percutaneous transluminal
15 angioplasty, percutaneous transluminal nephrostomy,
16 ureteral dilatation, biliary duct dilatation, percutaneous
17 transluminal renal angioplasty, and the like. Balloons
18 for use in these procedures have been prepared from a
19 variety of polymeric materials which are blood and tissue
20 compatible. Among those materials that have been employed
21 include materials such as poly(vinylchloride),
22 polyethylene and the like, homopolymers or copolymers of
23 olefins, polyethylene/vinyl acetate copolymers,
24 polyethylene terephthalate and polyurethanes.

25 Catheter balloons must be quite strong to withstand
26 significant inflation pressures. Accordingly, they
27 sometimes tend to be somewhat stiff, since their wall
28 thickness must be sufficient to provide the necessary
29 strength. Thus, when deflated, such catheter balloons can
30 flatten in a phenomenon known as "winging", in which the
31 flat, lateral portions of the deflated balloon project
32 laterally outward beyond the rest of the catheter. This
33 is deemed to be undesirable by many practitioners because
34 of a concern that the flat wings may damage, e.g. an
35 artery wall, as the deflated balloon is removed from the
36 arterial system. Also, such flat wings can interfere with

1 the manipulation of the catheter and its easy advancement
2 through the arterial system.

3 A recent attempt to solve the problem of winging has
4 been reported in U.S. Patent No. 4,941,811, which
5 describes a balloon catheter wherein the balloon defines
6 transition zones at the respective ends which are of a
7 rounded fluted shape. The flutes, typically from three to
8 eight, are described as generally longitudinally directed
9 at an angle to the balloon axis, and typically extending
10 at a mutually perpendicular radial angle to the axis, the
11 lateral angle being generally from 0 to about 45 degrees,
12 preferably about 10 to 30 degrees. The radial angle in
13 the as-molded balloon is described as dependent on the
14 length of the transition zone and the relative diameters
15 of the balloon and the connected catheter portions, being
16 typically about 10 to 45 degrees. These balloons are
17 prepared by a blow molding operation, wherein the shape of
18 the balloon is governed by the inner shape of the molding
19 chamber of the blow mold. Accordingly, the outer surface
20 of the balloons, at the transition zones, contains an
21 indentation which accounts for the grooves or flutes as
22 defined therein. Finally, it is noted that the central
23 portions of the catheter are directed into a mode of
24 collapse by the flutes which is generally similar to the
25 mode of collapse in the fluted transition zones, wherein
26 the projecting "wings" are then avoided along the entire
27 length of the collapsed balloon catheter.

28 While the above balloon apparently prevents a flat-
29 collapsed configuration of the balloon, it does not
30 contemplate the advantages of the instant invention, which
31 has found that an extremely small raised ribbed
32 configuration of essentially any geometry on the inner
33 surface of the balloon, wherein the ribs need only
34 maintain some minimal contact angle with the inner balloon
35 wall, can completely prevent a flat-collapsed
36 configuration of the balloon. Furthermore, the ribs as

1 defined run parallel along the entire longitudinal length
2 of the balloon and there is no need to specify a lateral
3 or radial angle of such ribs. Such a design also provides
4 for a much lower profile on any given catheter shaft that
5 the balloon is employed. Moreover, the inner surface
6 configuration described above can be manufactured by
7 extrusion methods.

8 In accordance with this invention, a balloon
9 configuration for a balloon catheter is provided, which
10 eliminates the undesirable winging phenomena that is
11 encountered when the catheter balloon is in a deflated
12 condition. Also, the catheter balloon is stronger than
13 prior art catheter balloons with improved tensile
14 strength, while exhibiting a reduced wall thickness to
15 improve the flexibility of the balloon. Thus, with the
16 catheter balloon of this invention, balloon catheter
17 procedures can be performed more effectively, with less
18 concern about damage to the patient's veins or arteries by
19 the "winging" phenomena of the deflated catheter balloon,
20 and with ease of catheter advancement through the veins or
21 artery system.

22 Accordingly, it is the object of this invention to
23 overcome the "wings" using a balloon design that will
24 collapse the balloon evenly around the catheter a full 360
25 degrees.

26 It is a further object of this invention to provide a
27 balloon design that is suitable for use with the variety
28 of polymeric materials that are used in dilatation balloon
29 catheterization.

30 Yet a further object of this invention is to provide a
31 balloon design that will collapse the balloon evenly
32 around the catheter a full 360 degrees while at the same
33 time being capable of production via standard plastic melt
34 processing techniques such as extrusion.

35 Still a further object of this invention is to provide
36 a relatively small, internally ribbed, raised level,

1 triangular, rectangular, square, circular or semi-circular
2 parallel protrusion along the complete longitudinal
3 internal surfaces of the dilatation balloon which can then
4 be employed in a balloon catheter for use in a dilatation
5 procedure such as angioplasty and the like, the internal
6 surface modified balloon catheters being capable of
7 withstanding higher pressures as compared to balloons
8 without internal surface modification, which also serves
9 to provide a lower profile balloon configuration.

10 These objects, and other objects which will become
11 apparent from the description which follows, are achieved
12 by the balloons and the balloon catheters of the invention
13 and by the methods for their preparation. Thus, in its
14 broadest aspect, the invention comprises balloons and
15 balloon catheters for use in medical dilatation procedures
16 wherein the materials employed for the preparation of the
17 balloons can be altered during their processing and
18 preparation into an elastic balloon configuration that
19 collapses evenly around the surface of a dilatation
20 catheter.

21 Summary of the Invention

22 The invention comprises a flexible plastic material in
23 an inflatable and collapsible medical dilatation balloon
24 and balloon catheter wherein the internal surface of the
25 balloon has been integrally formed with a longitudinal
26 geometry that prevents a flat-collapsed configuration of
27 the balloon. The internal surface of the balloon is
28 imparted with a small inwardly projecting raised-ribbed
29 configuration, substantially equally spaced about the
30 circumference of the balloon, the ribs also maintaining
31 some minimal contact with the internal surface of the
32 balloon so that they remain in place along the length of
33 the balloon. The geometry so formed on the internal
34 surface of the balloon also increases the pressure the
35 balloon will normally withstand when the balloon is
36 inflated to dilate a vein or artery. The internal surface

1 geometry can be manufactured during the extrusion of a
2 balloon tube.

3 Brief Description of the Drawings

4 FIG. 1 shows, in cross-section, an extruded tube
5 wherein the ribs are formed along the length of the
6 balloon;

7 FIG. 2 shows, in cross-section, another typical
8 balloon in accordance with the invention;

9 FIGS. 3A-3C show in plan and cross-sectional views
10 typical extrusion mandrel used to manufacture a typical
11 balloon in accordance with the invention.

12 FIG. 4 shows, in cross-section, a circular geometry of
13 the ribs on the internal surface of the collapsible
14 balloon;

15 FIG. 5 shows, in cross-section, a semi-circular
16 geometry of the ribs on the internal surface of the
17 collapsible balloon;

18 FIG. 6 shows, in cross-section, a rectangular geometry
19 of the ribs on the internal surface of the collapsible
20 balloon;

21 FIG. 7 shows, in cross-section, a triangular geometry
22 of the ribs on the internal surface of the collapsible
23 balloon;

24 FIG. 8 shows, in partial cross section, a balloon and
25 catheter in accordance with the invention;

26 Detailed Description of the Invention

27 The invention will now be described by reference to
28 the various specific embodiments which are shown in the
29 attached drawings. It is to be understood that these
30 embodiments are shown for purposes of illustration only
31 and are not to be construed as limiting.

32 The principal novelty in the medical dilatation
33 balloons and balloon catheters of the invention lies in
34 their internal surface geometry which has been integrally
35 formed with a longitudinal configuration that prevents a
36 flat-collapsed configuration of the balloon while at the

1 same time providing a balloon that is able to withstand
2 higher dilatation pressures. In addition, the medical
3 dilatation balloon catheters of the invention provide a
4 low profile on any given catheter shaft.

5 The balloons and balloon catheters of the invention
6 are prepared in a conventional manner using conventional
7 equipment and employing any of the conventional
8 elastomeric materials used in the fabrication of
9 dilatation balloon catheters. Accordingly, any of the
10 polymeric materials such as poly(vinylchloride), styrenic
11 polymers such as "KRATON", polyacrylates, polyoelfins,
12 polyamides, polyesters, fluoropolymers, silicones and the
13 like, conventionally employed in the art to prepare
14 dilatation balloon catheters, can be employed to fabricate
15 the dilatation balloon catheters of the instant invention.

16 For example, in producing a typical dilatation balloon
17 10 of the kind shown overall in FIGS. 1 and 2, a tube
18 having a wall thickness of about 0.05 mm to about 0.5 mm
19 and an internal diameter of about 0.8 mm to about 10 mm is
20 produced by extrusion of the aforesaid plastic materials
21 using conventional melt processing equipment. The
22 extruded balloon tube is formed by passing the tube over
23 an appropriate sized mandrel which first provides the
24 balloon with such precision wall thickness. At the same
25 time that the mandrel operates to form the balloon tube,
26 it can also be configured to cause the formation of the
27 desired inner surface geometry which is shown as ribs 11
28 in FIGS. 1 and 2. FIGS. 3A-3C illustrate an extrusion
29 assembly in plan in cross-section 12 a typical extrusion
30 mandrel which operates to form a plurality of radially
31 inwardly projecting ribs extending along the entire length
32 of the extruded balloon tube. The mandrel is inserted
33 into the extrusion die. A gap 13 is set between the die
34 and mandrel after insertion, this gap forming the wall of
35 the tube and also forms any design on the internal balloon
36 wall. It can be seen that the design 14 is cut into the

1 land area of the mandrel.

2 After extrusion, one end of an extruded balloon tube
3 is inserted into a mold having an internal configuration
4 corresponding to the external configuration of the desired
5 balloon. The balloon tube is then pinched off at one end,
6 the mold is heated above the softening temperature of the
7 flexible plastic material and a suitable gas such as
8 nitrogen is used to pressurize and inflate the softened
9 portion of the tube and force the walls thereof into
10 contact with the walls of the balloon.

11 In a more particular embodiment employing a material
12 such as a polyurethane, the tube is heated in the mold
13 described above to a softening temperature in the range of
14 about 60 degrees C to about 150 degrees C.

15 It has been found, in accordance with the present
16 invention, that any geometry of the internal ribs will
17 serve to prevent a flat-collapsed configuration of the
18 balloon. Accordingly, ribs that are triangular (FIG. 4),
19 rectangular (FIG. 5), square, circular (FIG. 6) or semi-
20 circular (FIG. 7), which lie parallel to one another along
21 the complete longitudinal length on the inner surface of
22 the balloon act to eliminate the "winging" effect
23 encountered in balloons which lack such an internal
24 surface modification. While the size and number of ribs
25 can be increased for other reasons as described below, it
26 has been found that at least three ribs are necessary to
27 avoid the "winging" phenomena, and in a more preferred
28 embodiment the balloons have at least four ribs.

29 Furthermore, the ribs may be extremely small, and in
30 the case of a rectangular configuration, the ribs have the
31 preferred dimensions of 0.005 inches (0.127 mm) deep by
32 0.003 inches (0.0762 mm) wide. In the case of a round
33 configuration, it has similarly been found that a
34 preferred diameter of 0.0005 inches (0.0127 mm) is
35 sufficient to prevent a flat-collapsed configuration. In
36 the broadest embodiment, it has been found that as long as

1 the ribs protrude about 0.0001 (0.00254 mm) inches into
2 the balloon, "winging" can be substantially eliminated.

3 Furthermore, for any of the ribs now described, the
4 ribs need only make minimum contact with the inner surface
5 of the balloon sufficient to keep the ribs in place in a
6 given medical dilatation procedure.

7 It has also been found that while the above dimensions
8 of the ribs serve to prevent a flat-collapsed
9 configuration of the balloon, the ribs also increase the
10 pressures that one can apply in a dilatation procedure,
11 again, relative to those balloons that do not contain such
12 ribs. Accordingly, an increase in the size of the ribs
13 will allow a further increase in the pressure that can be
14 employed in dilatation, while still maintaining complete
15 resistance to the development of a flat-collapsed
16 configuration when a vacuum is applied.

17 The actual dimensions of the balloons with a modified
18 internal surface geometry will depend upon the particular
19 dilatation procedure for which the balloon and any
20 attached catheter are to be employed. In general where
21 the balloon is to be used in angioplasty, the external
22 diameter of the balloon will be of the order of about 2 mm
23 to about 25 mm. The overall length of the inflated
24 portion will be of the order of about 10 mm to about 150
25 mm. The walls of the balloon will have an average
26 thickness in the range of about 0.01 mm to about 0.2 mm
27 depending in part on the pressures to which the balloon is
28 to be inflated in actual use.

29 As will be obvious to one skilled in the art, the
30 dilatation balloons of the invention can also be employed
31 to replace dilatation balloons in any of the many other
32 types of balloon-catheter combinations, with or without
33 guide wires, currently employed in medical dilatation
34 procedures. Referring to the drawings, FIG. 8 shows a
35 balloon catheter, which defines a tubular catheter body
36 15, a proximal hub 16, and a guide wire 17 which extends

1 through the catheter, all being of generally conventional
2 design. Catheter body 15 defines an inflatable and
3 collapsible balloon 18 of the invention with internal ribs
4 19, shown to be, as is conventional, in a tubular section
5 of relatively larger diameter than the rest of the
6 catheter body 15. Balloon 18 may be an integral part of
7 the rest of the catheter body 15, or it may be separately
8 manufactured, for example, by an extrusion process and
9 then attached to the remainder of the catheter body 15.
10 Balloon 18 may be entirely inflated to expand its
11 diameter, and may also be collapsed to a minimum diameter
12 while, by this invention, the formation of a flat "winged"
13 configuration may be avoided in the collapsed mode of the
14 balloon.

15 The balloons of the invention possess properties which
16 render them especially valuable in carrying out medical
17 dilatation procedures such as angioplasty and the like.
18 Thus, the walls of the balloon are sufficiently thin to
19 allow the balloon to deflate without a flat-collapsed
20 configuration, and to permit passage into and through the
21 artery, vein or like passageway involved in a medical
22 procedure. However, the walls of the balloon are
23 possessed of sufficient flexural strength such that the
24 balloon will not expand beyond the originally molded
25 configuration under pressures up to at least about 100 psi
26 or significantly higher depending upon the wall thickness
27 and/or overall size of the balloon. Hence, there is no
28 problem of uncontrolled expansion or danger of bursting
29 under pressure conditions routinely involved in
30 angioplasty and like procedures. Further, because the
31 balloons can be integrally molded on catheters of the same
32 material as that used for the balloon or, alternatively,
33 can be securely bonded without difficulty to other
34 materials employed in the formation of catheters, there is
35 little or no risk of rupture at the junction of balloon
36 and catheter while the dilatation procedure is being

1 carried out. Accordingly, the balloons and balloon
2 catheters of the present invention represent a significant
3 advance in the art.

4 The above has been offered for illustrative purposes
5 only, and is not intended to limit the scope of the
6 invention of this application, which is defined in the
7 claims below.

1 That which is claimed is:

2 1. An inflatable and collapsible balloon for use in a
3 medical dilatation catheter wherein the internal surface
4 of the balloon has been formed with at least three
5 radially inwardly projecting ribs (11) which extend
6 directly into the balloon and are integrally formed along
7 the complete longitudinal length of the inner balloon wall
8 and prevent a flat-collapsed configuration of the balloon.

9 2. The balloon of claim 1 wherein the radially
10 inwardly projecting ribs (11) are of a triangular,
11 rectangular, square, circular or semi-circular geometry.

12 3. The balloon of claim 1 wherein the inwardly
13 projecting ribs (11) are substantially equally spaced
14 about the circumference of the collapsible balloon.

15 4. The balloon of claim 1 wherein the inwardly
16 projecting ribs (11) are rectangular and are of the
17 dimensions 0.0127 mm deep by 0.0762 mm wide.

18 5. The balloon of claim 1 wherein the inwardly
19 projecting ribs project 0.00254 mm into the balloon.

20 6. The balloon of claim 1 wherein the balloon is
21 formed from a plastic material suitable for thermoplastic
22 melt processing.

23 7. The balloon of claim 6 wherein the balloon is
24 prepared from materials selected from the group consisting
25 of poly(vinylchloride), polyethylene, ethylene copolymers,
26 styrenic polymers, polyethylene/vinyl acetate copolymer,
27 polyethylene terephthalate, nylon elastomers, silicone
28 elastomers, fluoropolymer elastomers, and polyurethanes.

29 8. The balloon of claim 1 for use in the dilatation
30 catheter procedure of angioplasty.

31 9. A method for producing the balloon of claim 1
32 comprising:

33 a. extruding a flexible plastic material over a
34 mandrel which provides a tubular shaped extrudate wherein
35 the mandrel causes the internal surface of the balloon to
36 be integrally formed with a plurality of radially inwardly

1 projecting ribs; and

2 b. allowing the extrudate to cool to a
3 temperature to solidify; and

4 c. placing the extrudate into a blow molding
5 assembly wherein the tube is heated and expanded into the
6 mold into a desired balloon shape.

7 10. A catheter having a catheter body, a portion of
8 said body defining the inflatable and collapsible balloon
9 of claim 1.

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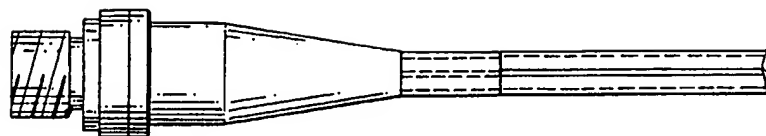
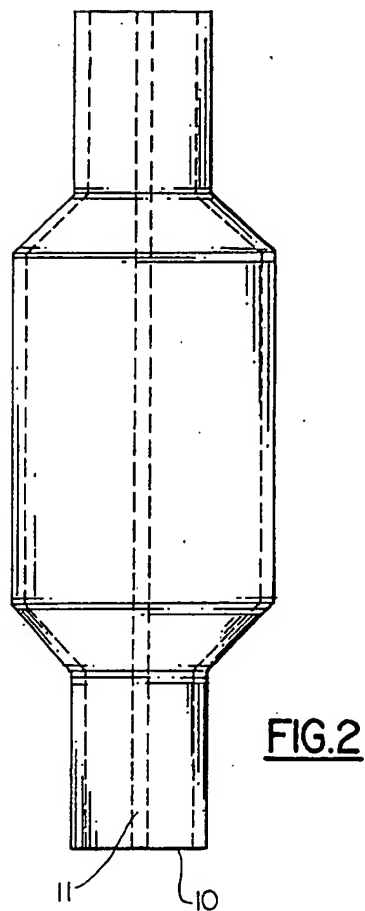
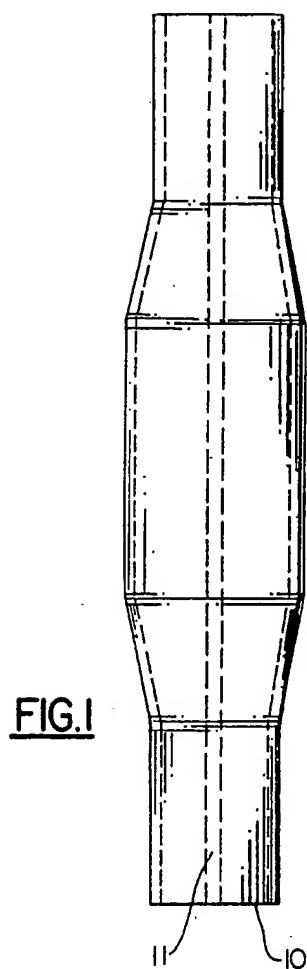


FIG.3A

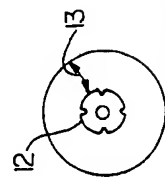
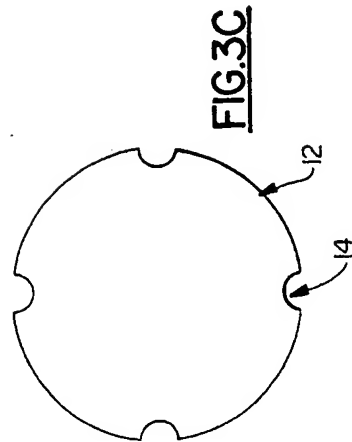
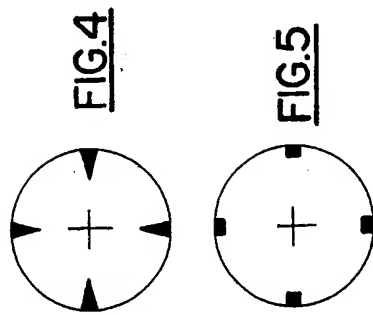
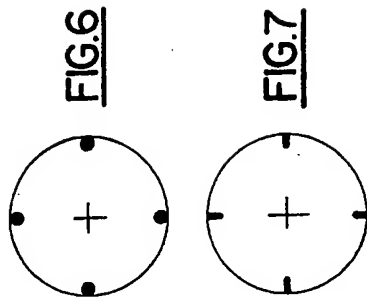


FIG. 3B

FIG. 3C

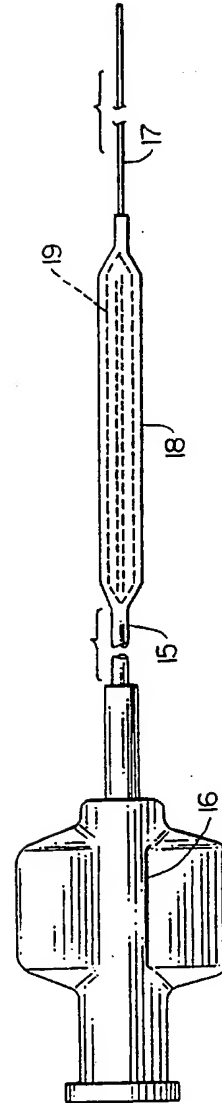
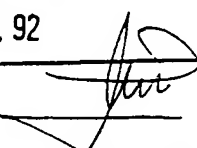


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 92/02970

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M25/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	GB,A,2 187 390 (COLLIER) 9 September 1987 see page 1, line 41 - line 45; figure 2 see page 1, line 103 - line 116 ---	1-8,10
X	FR,A,2 529 083 (FARCOT ET AL.) 30 December 1983 see page 5, line 12 - line 27; figures 3-6 ---	1-8,10
A	EP,A,0 414 350 (C.R. BARD, INC.) 27 February 1991 see column 7, line 25 - column 8, line 13; figures ---	9
A	US,A,2 248 934 (AUZIN) 15 July 1941 see page 1, left column, line 3 - line 40; figures ---	9
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
30 JULY 1992	12.08.92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V 	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. US 9202970
SA 58900**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A-2187390	09-09-87	None	
FR-A-2529083	30-12-83	FR-A- 2502499 US-A- 4459977	01-10-82 17-07-84
EP-A-0414350	27-02-91	JP-A- 3092173	17-04-91
US-A-2248934		None	